

Tixylix Dry Cough – PL 44673/0175 – leaflet

Tixylix Dry Cough

Pholcodine

PACKAGE LEAFLET: INFORMATION FOR THE USER

Cough and Cold in children

It is usual for children to get several colds a year. As they get older, their immunity builds up and they get fewer colds. Most colds will get better within a few days and you may not need to do more than keep your child comfortable until they get over it.

Fever: If they are feverish, give them plenty of fluids to drink. Their temperature may be lowered with a suitable medicine which has doses for children. For further advice, talk to your healthcare professional.

Coughs: Although it can be distressing to hear your child cough, in fact this helps to clear phlegm from the chest and mucus from the nose. Give your child plenty of warm clear fluids.

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without a prescription. However, you still need to give Tixylix Dry Cough carefully to get the best results from it.

- . Keep this leaflet. You may need to read it again.
- . Ask your pharmacist if you need more information or advice.
- . You must contact a doctor if your child's symptoms worsen or do not improve after 5 days.
- . If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet.

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1. WHAT TIXYLIX DRY COUGH IS AND WHAT IT IS USED FOR

Tixylix Dry Cough is an oral cough suppressant for the relief of dry, tickly coughs in children, and contains pholcodine as the active ingredient.

Each 5 ml dose of Tixylix Dry Cough contains pholcodine 4 mg.

This medicine is intended for use in children aged 6 to 10 years. It is not suitable for adults and children aged over 10 years.

2. BEFORE YOU GIVE TIXYLIX DRY COUGH

Do not give Tixylix Dry Cough if

- . your child is allergic (hypersensitive) to any of the ingredients of Tixylix Dry Cough (see Section 6),
- . you have been told by your doctor not to stop your child coughing.
- . your child is under 6 years of age
- . your child is experiencing or is at risk of respiratory failure

- . your child has chronic bronchitis, chronic obstructive pulmonary disease (COPD), bronchiolitis or bronchoiectasis (widening of the tubes in the lung) due to sputum retention.
- . your child is taking monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping such treatment

Take special care with Tixylix Dry Cough

Consult your doctor or pharmacist if your child:

- . is taking other medicines, including those which suppress the central nervous system and alcohol
- . is suffering from liver or kidney disease
- . is suffering from a chronic or persistent cough or where the cough is accompanied by excessive secretions
- . is suffering from asthma or an acute asthma attack

Taking other medicines

Please tell your doctor or pharmacist if your child is taking, or has recently taken, any other medicines, including medicines obtained without a prescription, including medicines for blocking the nerves or muscles, monoamine oxidase inhibitors (MAOIs), medicines for reducing blood pressure, diuretics, alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives or tranquillisers (phenothiazines and tricyclic antidepressants)

Taking Tixylix Dry Cough with food and drink

There are no specific requirements for taking Tixylix Dry Cough with food or drink

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.
This medicine is not intended for use in adults and children over 10 years.

Driving and using machines

This medicine is not intended for use in adults and children over 10 years. Tixylix Dry Cough may cause drowsiness.

Important information about some of the ingredients of Tixylix Dry Cough.

This medicine contains the following additional ingredients:

- . Malitol - if you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before taking this product.
- . Glycerol - may cause stomach upsets and diarrhoea in high doses.
- . Sodium benzoate (E211) may be a mild irritant.
- . Sweeteners - acesulfame potassium and sodium saccharin.

WARNING: Do not exceed the stated dose. Do not take with any other cough and cold medicine.

3. HOW TO GIVE TIXYLIX DRY COUGH

Always give Tixylix Dry Cough exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Shake well before use. Using the measuring spoon provided, the following doses may be given 2 to 3 times daily, by mouth, as required. **Do not exceed four doses in 24 hours.**

After use, wipe the neck of the bottle clean and make sure the safety cap is properly closed.

Parents or carers should seek medical advice if the child's condition deteriorates during treatment.

Age	Dose
6 to 10 years	One to two 5 ml spoonfuls

If you give more Tixylix Dry Cough than you should

Giving your child too much Tixylix Dry Cough may cause restlessness, loss of co-ordination, or excitement. In very rare cases a decrease in the number of breaths and the depth of breathing (respiratory depression) or pin-point pupils may occur. Taking alcohol or drugs which affect your mental state are likely to worsen the effects of overdose. If you have accidentally given your child more medicine than you should, or if you suspect that your child has taken extra medicine, please contact your doctor or hospital. Take along the bottle and the label, and any medicine that is left.

If you forget to give Tixylix Dry Cough

Do not give your child a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Tixylix Dry Cough can cause side effects, although not everybody gets them.

Tixylix Dry Cough can cause nausea, drowsiness, dizziness, excitation, confusion, constipation and skin reactions such as rash, hypersensitivity reactions or anaphylaxis (severe allergic reaction) may also occur. If any of the side effects gets serious, or if your child has any side effects not listed in this leaflet, please tell your doctor or pharmacist

5. HOW TO STORE TIXYLIX DRY COUGH

Keep out of the reach and sight of children.

Do not store above 25°C. Keep the container tightly closed.

Do not use Tixylix Dry Cough after the expiry date which is stated on the carton and the bottle label after <EXP>.

The expiry date refers to the last day of that month.

Medicine should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FUTHER INFORMATION

What Tixylix Dry Cough contains

The active ingredient is pholcodine. The other ingredients are liquid maltitol (Lycasin), sodium benzoate (E211), citric acid, acesulfame potassium, natural flavours (blackcurrant, vanilla), purified water.

What Tixylix Dry Cough looks like and contents of the pack

Tixylix Dry cough is a colour-free oral solution.

The following pack sizes are available:

100 ml amber-coloured glass bottle with either a tamper-evident cap or a child resistant cap.

1000 ml amber-coloured glass bottle with either a tamper-evident cap or a child resistant cap.

Measuring spoon provided.

Marketing Authorisation Holder

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, Brentford, TW8 9GS, U.K.

Manufactured by

BCM Limited, Nottingham, NG90 2PR

For any information about this medicinal product, please contact the Marketing Authorisation Holder.

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